JUN 0 4 2013

510(k) Summary
As required by 21 CFR §807.92(c)

Submitter

510(k) Owner:	Intel-GE Care Innovations™
Address:	3721 Douglas Boulevard, Suite 100, Roseville, CA 95661
Telephone:	(916) 847-7794
Contact Person:	Maureen Glynn
Date Prepared:	January 31st, 2013

Device Information

Trade Name:	Modification to Intel-GE Care Innovations Guide
Common Name:	Remote Patient Monitoring System
Classification Name:	Transmitters and Receivers, Physiological Signal, Radiofrequency (21 CFR 870.2910, Product Code DRG)

Substantial Equivalence is claimed to the following device:
Intel-GE Care Innovations Guide (aka Intel® Health Guide Express) **(K103276)**

Device Description

The Intel-GE Care Innovations Guide is a communication tool that allows caregivers to remotely access vital sign measurements of patients at home. The Intel-GE Care Innovations Guide is a software application running on a Commercial Off The Shelf (COTS) Personal Computer (PC). It collects measurements captured on commercially available wireless or tethered medical devices which are designed for home use and connection to a COTS PC. It displays the collected measurement on the PC, and securely stores the collected information locally on a memory device installed in the PC. Intel-GE Care Innovations Guide also stores the information remotely on a host server, where the caregiver can view the measurement via the host server once synchronization between the host server and Intel® Health Guide

Express has been completed. Intel-GE Care Innovations Guide can be used to display educational and motivational content from the caregiver and can facilitate communication between the caregiver and patient via health wellness surveys and optional video conferencing.

The Intel-GE Care Innovations Guide is not interpretive, nor is it intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required. It is contraindicated for patients requiring direct medical supervision or emergency intervention. It is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.
The Intel-GE Care Innovations Guide system consists of the:

(1) Intel-GE Care Innovations Guide software application:

The software application captures, stores, displays and transmits information to a secure database on a host server running the Intel-GE Care Innovations Health Care Management Suite software via a standard telephone line or internet connection. The Intel-GE Care Innovations Guide software runs on a Commercial Off The Shelf (COTS) Personal Computer (PC).

(2) Intel-GE Care Innovations Health Care Management Suite software application:

The software application runs on a host server and allows caregivers to review patient vital signs on the secure website. The Intel-GE Care Innovations Health Care Management Suite allows for predefining upper and lower limits and, when either limit is exceeded, the system emails and/or pages the caregiver.

Indications for Use

The Intel-GE Care Innovations Guide is intended to collect vital sign measurements from physiological measurement devices intended for use in the home. Patients can review the stored vital sign measurement information and receive educational and motivational content from caregivers. Patients can also engage in video conferences with caregivers and answer the caregivers' questions by participating in surveys.

The Intel-GE Care Innovations Health Care Management Suite allows the caregiver to review patient data and initiate video conferencing with patients, or select and send educational and motivational content to patients.

The Intel-GE Care Innovations Guide is not interpretive, nor is it intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required.

The Intel-GE Care Innovations Guide is contraindicated for patients requiring direct medical supervision or emergency intervention. It is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

Technological Characteristics

The Intel-GE Care Innovations Guide is substantially equivalent to the predicate device in terms of data collection software functionality, operating system for the patient device, communication method of patient device with central server, types of sensors which can be interfaced to the patient device, implementation method of collecting data from sensors, sensor software, connectivity, communication protocol, power source, and display method.

Safety and Efficacy

The Intel-GE Care Innovations Guide does not rely on an assessment of clinical performance data. The device conforms to FDA's recognized consensus standards and relies on its conformity to demonstrate the safety and efficacy. The device introduces no new questions concerning the safety or efficacy and is, therefore, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 4, 2013

Intel-GE Care Innovations LLC
c/o Ms. Maureen Glynn
Director of Regulatory Affairs
3721 Douglas Boulevard, Suite 100
Roseville, CA 95661

Re: K130290
Trade/Device Name: Modification to Intel-GE Care Innovations Guide
Regulatory Number: 21 CFR 870.2910
Regulation Name: Transmitters and Receivers, Physiological Signal, Radiofrequency
Regulatory Class: II (two)
Product Code: 74 DRG
Dated: April 23, 2013
Received: April 26, 2013

Dear Ms. Glynn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K130290

Indications for Use:

510(k) Number: _____

Device Name: Intel-GE Care Innovations™ Guide

Indications for Use:

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Prescription Use _____ AND/OR Over-The-Counter Use ____X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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